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## Background

- The Division of AIDS Cross-Network Transgender Working Group recommended use of the two-step method across all NIH funded HIV/AIDS clinical trials networks in 2015
- The two-step method separates questions about sex assigned at birth and gender identity and provides multiple choices for responding
- Use of the two-step method affirms and acknowledges people for who they are
- The collection of gender identity data allows for a more accurate assessment of HIV treatment and prevention interventions in transgender communities

## IMPAACT Pilot of the Two-Step Method

- A pilot study was conducted in 2017 to assess the feasibility of using an interview case report form for collecting gender identity and sex assigned at birth in children and adolescents aged eight to 24 years
- 10 IMPAACT sites were invited to participate in the pilot; 4 actually participated
- Participating sites: Bangkok, Thailand; Fort Lauderdale, FL; Chicago, IL; Denver, CO
- Participants were asked about:
  - sex at birth
  - gender identity
  - how well questions were understood
  - how easy or difficult it was to answer the questions
  - suggestions for better ways to ask these questions

## Finding from Pilot

- Overall the questionnaire was well-understood and easily completed by most of the 32 respondents
- Understanding cultural differences and risks are important
  - The Brazilian National Commission on Research Ethics (CONEP) did not approve participation in the pilot due to "risk of discrimination, stigma, violence and other harmful consequences"

## Proposal to IMPAACT Leadership

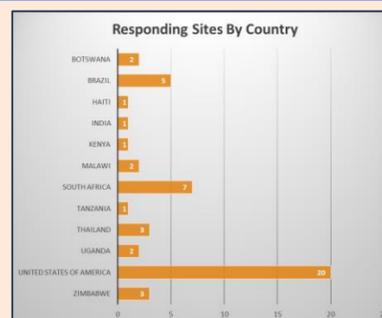
- Based on results of the pilot and consultations with subject matter experts, a proposal was made to IMPAACT leadership
- All protocols including youth 12 years and older will assess gender identity
  - Youth under the age of 12 will not be asked about their gender identity given concerns about the validity of the two-step approach in this age group
  - Unless specified in the protocol, gender identity would only be collected once for children 12 years and older at time of entry
- Any site can opt-out of asking about gender identity if:
  - They have safety concerns about assessing gender identity in youth (12 and older), or
  - There are no local resources available for referral should the need arise

## Implementation of the Two-Step Method

- Data on sex assigned at birth will be obtained from the medical record
- Gender identity will be asked in a face-to-face, confidential interview without a parent or guardian present
- Collection of gender identity data will be added to the informed consent
- Training resources for site staff will be included in the protocol Manual of Operations
- Requests from protocol teams to not include gender identity data collection requires approval from IMPAACT Scientific Leadership Group (SLG)

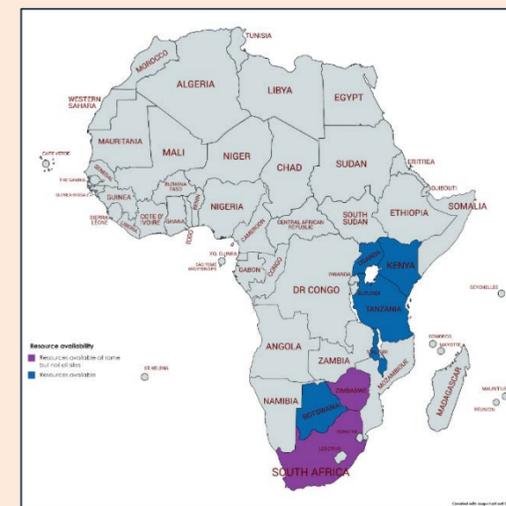
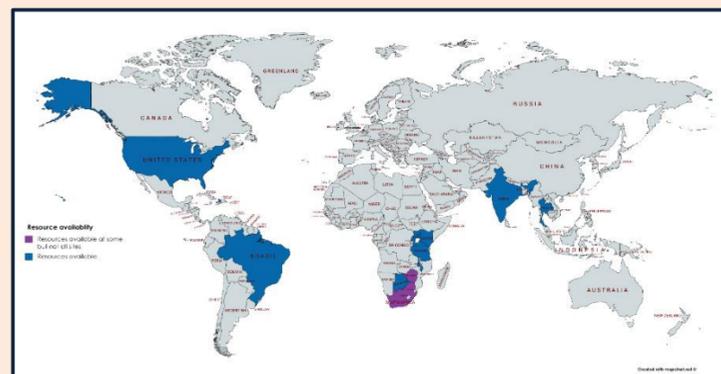
## Site Survey

- Site survey conducted in IMPAACT Network to better understand:
  - Availability of resources and related costs
  - Discrimination/stigma
  - Legal concerns
- All 48 sites responded
- Surveys were completed by a wide range of site personnel



## Awareness & Cost of Trans-competent Resources/Services

- Vast majority of sites have or are aware of resources that would be available for participants (92%; 44/48)
- Resources included psychiatrists, psychologists, other mental health providers, pediatric nurses and specialists, among others at the institution or in the community
- 13/42 sites (31%) said there would be a cost involved in accessing resources (two sites did not respond)
- 6/13 sites (46%) were not sure whether participants would be able to pay for services



## Legal Issues

- 15% of the sites surveyed (7/48) said that there may be legal issues related to disclosure of gender identity to staff
- The issues identified related to:
  - Lack of legal protections and lack of government support
  - Interpretation that study is promoting LGBT practices
  - Need to use legal name on informed consent documentation
  - Need for IRB approval
- One US-based institution uniquely noted a hospital policy that prohibits asking about sex assigned at birth, gender identity or transition-related interventions unless it is necessary to patient care

## Safety Concerns

- 13% of the sites (6/48) indicated that discrimination may result from disclosure to staff
- Comments included the fear of stigma, discrimination, violence and isolation
- 4/6 sites (67%) said participants might be reluctant to disclose gender identity
- Reasons included: fear of discrimination; concern about adequacy of confidentiality; and the complexity of acknowledging their gender status even to themselves
- 2/6 sites (33%) said that while safety is of concern, they didn't think it posed a barrier to asking about gender identity

*"Transgender individuals may be hesitant to disclose their gender identity to site staff without adequate assurance of confidentiality, acceptance, and no loss of privileges"*

*"Fear of stigma and discrimination may affect the quality of data collected since some of the information may be concealed by participants"*

## Other Barriers

- 9/48 sites (19%) said there were other issues/barriers that needed to be considered, including:
  - IRB approval
  - Discrimination, stigma, cultural and religious beliefs in the community
  - Limited awareness of different gender identities; the concept of gender identity itself considered a "Western idea"
  - Discomfort speaking in front of caregiver
  - Hospital policy

*Cultural and religious beliefs are constraints to providing LGBT services*

## Other Comments

- 14/48 sites (29%) included additional comments, roughly half of which were supportive of asking about gender identity
- Concerns included the added burden on site personnel; costs associated with referrals; community expectations for more wholistic, gender-affirming care; fear of parents' lack of acceptance; and the appropriateness of asking about gender identity
- Supportive comments noted the site's ability to ask about gender identity given previous experience, confidentiality of data, availability of mental health services, youth CAB support, policies prohibiting discrimination, and value of training

*"Any discussion of gender identity could lead to issues with discrimination and safety. However, our institution has a policy against discrimination on the basis of gender identity"*

*"We believe we can implement questions regarding gender identity with the appropriate training on culture and diversity"*

*"Our site has experience working with participants with varied gender identities... and a youth CAB sensitive and knowledgeable about youth who are MSM and transgender"*

## Conclusions & Next Steps

- Majority of sites surveyed felt that they would be able to implement the two-step method to obtain information about participants' gender-identity
- While some sites already have experience doing this, others noted that implementation would require staff training and guidance
- Vast majority of sites were aware of resources within their institution or community for trans-competent services should issues of gender dysphoria or other issues arise
- Some sites, particularly in Africa, noted that stigma, discrimination and legal issues are of concern; a number of them still believe that this did not preclude asking about gender identity
- Based on survey results, consultations, and research, the IMPAACT Management Oversight Group approved implementation of the two-step method; moving forward it will be incorporated into studies currently in development

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